K05/245

JUN 17 2005

SECTION 1 510(k) Summary

SUBMITTED FOR:

Company Name: **Proxy Biomedical, Ltd.**
Address: Unit 6D, Mervue Business Park
Galway, IRELAND
Contact Person: Peter Mulrooney, Quality Assurance Manager

Tel: +353 (0)91 709161 Fax: +353 (0)91 709162

Submitted by: Elaine Duncan, M.S.M.E., RAC
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
715-549-6035
715-549-5380

CONTACT PERSON: Elaine Duncan
DATE PREPARED: May 11, 2005
TRADE NAME: Polyform™ Synthetic Mesh
COMMON NAME: Surgical Mesh

SUBSTANTIALLY EQUIVALENT TO: Polyform™ Synthetic Mesh is substantially equivalent to the Mersilene Mesh (Ethicon, Inc.), the Prolene Soft Mesh (Ethicon, Inc.), and the Bard Mesh (C.R. Bard, Inc.) a polypropylene mesh.

DESCRIPTION of the DEVICE:
The Polyform™ Synthetic Mesh is a non-absorbable synthetic mesh, constructed of knitted filaments of Polypropylene. Polyform™ Synthetic Mesh is supplied sterile and provided in sheet form to be cut to size and sutured by the surgeon to meet the individual patient's needs. The mesh is approximately 0.0075" thick, and exhibits high burst strength and tensile strength. The Polyform™ Synthetic Mesh is knitted by a process which provides for elasticity in both directions. Use of Polyform™ Synthetic Mesh allows a fibroblastic response through the interstices of the implant, forming a strong fibrous wall.

INDICATIONS FOR USE:
The Polyform™ Synthetic Mesh is intended for tissue reinforcement and stabilization of fascial structures of the pelvic floor in vaginal wall prolapse, where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

SUMMARY of TESTING:
Bench test data reveal Polyform™ Synthetic Mesh has mechanical and material characterization values that are substantially equivalent to the predicate devices. The biocompatibility test results show that the material used in the design and manufacture of the device is non-toxic and non-sensitizing to biological tissues consistent with their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2005

Proxy BioMedical Ltd.
C/o Ms. Elaine Duncan, M.S.M.E., RAC
President, Paladin Medical Incorporated
P.O. Box 560
Stillwater, Minnesota 55082-0560

Re: K051245
Trade/Device Name: Polyform™ Synthetic Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: May 11, 2005
Received: May 16, 2005

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051245

Indications for Use

510(k) Number (if known):

Device Name: **Polyform™ Synthetic Mesh**

Indications For Use:

Polyform™ Synthetic Mesh is intended for tissue reinforcement and stabilization of fascial structures of the pelvic floor in vaginal wall prolapse, where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

Prescription Use ___✖___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K051245